K120284

7. 510(K) SUMMARY

MAY 2 3 2012

510(k) Owner/Submitter	Coloplast A/S; Division: Coloplast Corp Holtedam 1, Humlebaek 3050 – Denmark FDA Establishment Registration Number: 2125050
Contact	Janell A. Colley Coloplast Corp 1601 West River Road North Minneapolis, Minnesota 55411 USA
Date Prepared	30 January 2012
Common name/ Classification (current/proposed)	Delivery Device: surgical instrument, 878.4800, Instrument, ligature passing and knot tying Current Suture Cartridge: surgical suture, 878.5010; Nonabsorbable polypropylene surgical suture Proposed Suture Cartridge
Proprietary Name	Digitex Suture Delivery System (SDS); Digitex Delivery Device, Digitex Suture Cartridge
Predicate Devices	Digitex System: Digitex Suture Delivery System: K093112 Proposed Digitex Suture Cartridge predicates: Deknatel Deklene II suture, K930738; Monodek PDO suture, K030212; Bondek PGA suture, K991191 & K992088

Device Description

The Digitex SDS is composed of delivery device and suture cartridge and is designed for use by the physician to facilitate the consistent placement of suture when direct visualization is not possible and/or the anatomical location is difficult to reach. The shaft of the delivery device has been designed to allow for adjusting the angle of the needle housing to further facilitate suture placement in the desired location. The suture cartridges are provided pre-loaded with non-absorbable polypropylene, absorbable polydioxanone, or absorbable polyglycolic acid coated suture.

Intended Use

The Digitex Delivery Device is a sterile, disposable device intended to deliver a suture to the operative site. The device assists in suturing by passing a needle through the tissue to capture the suture, and suture ligation and knot-tying by holding the suture.

The Digitex Suture Cartridge holds sterile suture indicated for soft tissue approximation.

Technological Characteristics Compared to Predicate

The Digitex Suture Delivery System has the same intended use and fundamental scientific technology as the predicates Digitex Suture Delivery System: K093112, Deknatel Deklene II suture, K930738; Monodek PDO suture, K030212; and Bondek PGA suture, K991191 & K992088.

Summary Of The Nonclinical Tests Submitted

The modifications to the Digitex Suture Cartridges, specifically, adding suture cartridges with polydioxanone and polyglycolic acid coated absorbable suture, were evaluated via design verification testing and simulated use tests in a cadaveric laboratory. These tests confirmed that the Digitex Suture Cartridges, as modified, meet the established design specifications and are substantially equivalent to the predicate polypropylene Digitex Suture Cartridges. The predicate Digitex Suture Cartridges were subjected to biocompatibility testing to support the original 510k (K093112) and acceptable results from this testing apply to the proposed absorbable Digitex Suture Cartridges; additional evaluation and testing was conducted and acceptable results from this testing further demonstrate the acceptable biocompatibility profile of the proposed absorbable Digitex Suture Cartridges. The sterilization method and sterility assurance lever (SAL) have not changed; the change to the contract sterilization facility and modified sterile barrier have been evaluated and meet the requirements of ISO 11135 and ISO 10993-7.

Summary Of Clinical Tests Submitted (As Applicable)

Not applicable

Conclusions Drawn From The Nonclinical Tests

The Digitex Suture Delivery System is substantially equivalent to the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Coloplast A/S
% Ms. Janell Colley
Regulatory Affairs Manager
1601 West River Road North
Minneapolis, Minnesota 55411

MAY 23 2012

Re: K120284
Trade/Device Name: Digitex Suture Delivery System (SDS)
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable poly (glycolide/L-lactide) surgical suture
Regulatory Class: Class II
Product Code: NEW,GAM
Dated: April 20 , 2012
Received: April 23, 2012

Dear Ms. Colley

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

6. STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K120284

Device Name: Digitex Suture Delivery System (SDS)

Indications for Use:

The Digitex Delivery Device is a sterile, disposable device intended to deliver a suture to the operative site. The device assists in suturing by passing a needle through the tissue to capture the suture, and suture ligation and knot-tying by holding the suture.

The Digitex Suture Cartridge holds sterile suture indicated for soft tissue approximation.

Prescription Use ___X___ Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) AND/OR (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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